

NordicNeuroLab AS
Bergen, Norway

510(k) Summary

MAY 16 2008

510(k) Type: Special: Device Modification
Submission Date: 02.18.2008

Submitter: NordicNeuroLab AS
Møllendalsveien 65C
N-5009 Bergen
Norway

Phone: +47 55 70 70 95
Fax: +47 55 70 70 96
E-mail: stian@nordicneurolab.com

Contact: Stian Scisly Sagevik
Møllendalsveien 65C
N-5009 Bergen
Norway

Direct: +47 95 20 37 87
Phone: +47 55 70 70 95
Fax: +47 55 70 70 96
E-mail: stian@nordicneurolab.com

Legally marketed Device name and 510(k) number: fMRI Hardware System. K073099

Modified Device Name: fMRI Hardware System
Device Common Name: Accessory to MRI System, Nuclear Magnetic Resonance Imaging
Basis for Submission: Device Modification with a new software

Classification Regulation: 21 CFR 892.1000

Class: II
Panel: Radiology
Product Code: LNH

Trade/Proprietary Name: fMRI Hardware System

Device Description

3.1. Intended Use

The NordicNeuroLab fMRI Hardware System is a stimulus presentation and response collection system intended to be used by trained professionals to facilitate auditory and visual stimulation to evoke physiological processes detectable by the MRI scanner and to collect behavioral responses from the patient. These data, when interpreted by a trained physician, may assist in the diagnosis of brain pathology and may be used in the planning and monitoring of medical treatments.

This is the same intended use as previously cleared for the fMRI Hardware System, K073099.

3.2. System Description

The system presents auditory and visual stimulus to the patient and the patient gives feedback through a pair of handheld grips. A synchronization module synchronizes the nordicAktiva stimulus presentation software with the MR scanner. The System consists of five subsystems: AudioSystem, VisualSystem, ResponseGrip, SyncBox and nordicAktiva.

The intended use of the system is to support fMRI studies. fMRI stands for functional Magnetic Resonance Imaging. This technique is useful when determining certain diseases, gaining more information about a patient's condition or investigating cognitive functions. The technique is also used to patients suffering from a brain tumor in both the pre-operative and post-operative stage by examining the area of the brain affected.

The System is used to present the stimulus necessary to provoke physiological processes in the brain. Visual [VisualSystem] and auditory [AudioSystem] stimulus and manual responses from the patient [ResponseGrips] are of primary interest. As the timing of the data is critical to make sure that the correct MR image of the brain activity is linked to the stimulus presented, a synchronization unit [SyncBox] connected between the MR-scanner and the PC running nordicAktiva, a stimulus presentation software, is included in the System to make sure that the synchronization is correct.

The stimulus presentation PC hardware is not a part of the system.

Figure 1 presents the complete configuration of the fMRI Hardware System. All signals entering or leaving the scanner room are received and transmitted by use of fiber optics. The system allows video and audio signals from the stimulus PC to enter the shielded scanner room and to be presented to the subject lying inside the MR. The subject responds to the stimulus by using the handheld grips.

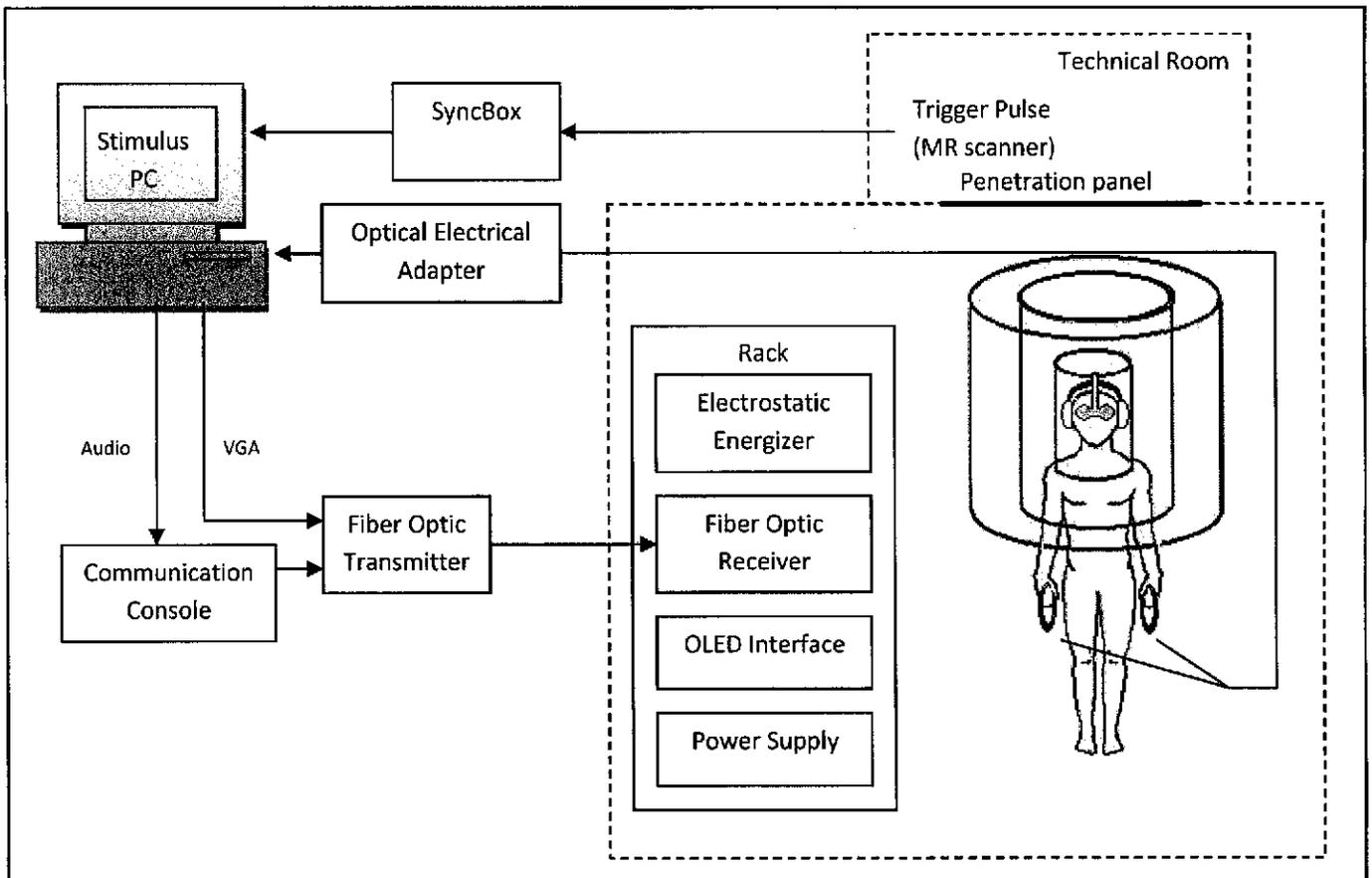


Figure 2: Complete configuration

3.3. Sub-system components and description

3.3.1. VisualSystem

The VisualSystem allows video signals from the stimulus presentation PC to enter the shielded scanner room and to be presented to the patient through a set of coil-mounted displays.

3.3.2. AudioSystem

The AudioSystem allows auditory signals from the stimulus presentation PC to enter the scanner room and to be presented to the patient wearing a set of headphones. A communication console allows the operator to adjust the sounds from the PC and to speak directly to the patient through a built-in microphone.

3.3.3. ResponseGrip

The purpose of this component is to collect patient responses during an fMRI study. The ResponseGrip consists of two hand-held grips with two buttons each. By pressing the buttons the patient can respond to the presented stimulus. The ResponseGrip is connected to an optical-

electrical adapter which converts light to electrical signals. The electrical signal is fed to the Stimulus PC by using standard PC communication interfaces.

3.3.4. SyncBox

The SyncBox is connected directly to the MRI scanner where it receives timing pulses sent out with each image series and demodulates this signal before it's forwarded to the stimulus PC. In this way one can ensure that the stimulus presentation software is synchronized with the MRI image recordings.

3.3.5. nordicAktiva

nordicAktiva is a software that generates visual and auditory stimulus to the patient. The stimulus presentation is synchronized with the scanner through the SyncBox, and presented to the patient through the VisualSystem and AudioSystem. nordicAktiva records the responses fed to the Stimulus PC from the ResponseGrip, as well as the synchronization pulses from the SyncBox.

3.4. Identification of Change to Unmodified Device

Special presentation software running on a PC connected to the fMRI Hardware System is required to run the stimulus presentation and to record and collect data on responses from the patient. Previously the end-user have been required to attain such software to be used with the system

Now such stimulus presentation software have been amended to the fMRI Hardware System as a subsystem and named nordicAktiva. This software provides the same basic functionality for stimulus presentation and data recording of the software currently used with the system.

The addition of the software nordicAktiva to run stimulus and record responses on the stimulus presentation PC is the only modification made to the fMRI Hardware System.

3.5. Statement of Substantial Equivalence

To summarize, the modified fMRI Hardware System is found substantial equivalent to the previously cleared device. The modified system only amends a software package that the end users are required to attain from other 3rd party software vendors today, and with that the indications for use have remained unchanged for the modified fMRI Hardware System.

3.6. Summary of Testing

The fMRI Hardware System has been tested for function and safety and fulfills all requirement specifications.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2008

Mr. Stian Scisly Sagevik
Quality Manager
NordicNeuroLab AS
Møllendalsveien 56C
N-5009 Bergen
NORWAY

Re: K080515

Trade/Device Name: fMRI Hardware System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: April 2, 2008
Received: April 7, 2008

Dear Mr. Sagevik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

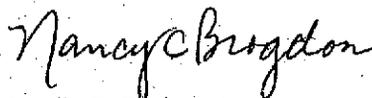
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080515

Device Name: fMRI Hardware System

Indications for Use:

The fMRI Hardware System is a stimulus presentation and response collection system intended to be used by trained professionals to facilitate auditory and visual stimulation to be used in functional MR Imaging (fMRI) based on BOLD contrast.

Prescription Use X

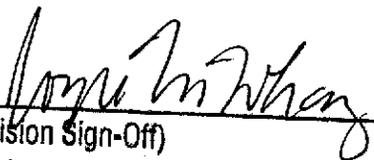
(Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page ___ of ___



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K080515 Indications for Use

Special 510(k) fMRI Hardware System

Attachment 2